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EXAMINER	
GOLLAMUDI, SHARMILA S	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 06/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/745,095	APPEL ET AL.	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *58-62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,7-9,12,15-32,44,49-51,56,57,63-81,88-97,101,103-108,118-122,124,130 and 131.* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 2,7-9,12,15-32,44,49-51,56,57,63-81,88-97,101,103-108,118-122,124,130 and 131.

DETAILED ACTION

Receipt for Request for Reconsideration and Amendments received on 4/25/05 is acknowledged. Claims **2,7-9,12,15-32,44,49-51,56,57,63-81,88-97,101,103-108,118-122,124,130 and 131** are pending in this application. Claims 58-62 stand withdrawn as being directed to a nonelected species.

Election/Restrictions

It should be noted that Restriction Requirement of 10/29/01 is rescinded and applicant may resubmit the previously withdrawn claims. However, the species requirement with regard to the drug is maintained.

Claim Objections

Claims 64-66 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Amended independent claim 2 is directed to a controlled release device that comprises a "low-solubility drug" and dependent claims 64-66 are directed to a low-solubility drug. Thus, the claims fail to further limit the parent claim since "a low-solubility drug" is a claim limitation in the parent claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 118-119 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Amended independent claim 2 is directed to a controlled release device that comprises a "low-solubility drug" and recites "said drug is not in the form of a solid dispersion". However, 118-119 are directed to a drug that is in a solid dispersion form. Claims 118-119 contradict the claims limitation of the parent claim; thus the claims limitations are indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2, 7-9, 12-32, 44-45, 49-51, 56, 63-81, 88-97,101, 103-108, 118-122, 124, and 130-131 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al (4,765,989) in view of Stevens et al (5,897,874), optionally in further view of Park et al (6,271,278).

Wong et al teach an osmotic device for administering drugs in various shapes and forms. The object of the device is to provide a therapeutic device that administers a complete pharmaceutical regimen at a controlled and continuous time period. The device also provides dispending to the gastric tract at a controlled rate. See column 3. The device contains a first composition containing a drug, polyethyleneoxide (PEO) (drug entertaining agent), hydroxypropylmethylcellulose (HPMC) (concentration enhancing polymer), and magnesium stearate. The second expanding composition contains PEO (swelling agent), instant HPMC tabletting aid), sodium chloride, and magnesium stearate. Nifedipine is utilized in the examples, which is a low-solubility drug and the drug is not in a solid dispersion form. See examples, especially 3. The osmopolymers are swellable and hydrophilic polymers, which swell and expand in aqueous medium. See column 15, lines 61-68. The osmopolymers used in the invention have an expansion and are utilized in both the firstly layer and second layer, which may be different or the same (col. 16, lines 3-5). The osmopolymers utilized may be a variety of hydrophilic polymers such as PEO polymers or a mixture of methylcellulose, crosslinked agar and carboxymethyl cellulose. See column 16, lines 20-23 and line 36. The mass ratio of the first composition to the second composition is taught on column 16. The general concept of swelling ratio is taught on columns 17 and 18. Wong teaches the active agent may in various forms and dispersed in suspending agents such as PVP (col. 18, line 43 to col.19, line 5). Agents such as tartaric acid (solubilizers), mannitol (fluidizers), sucrose, and sodium chloride are taught. The reference teaches a semipermeable wall that allows water to enter the core. A semipermeable wall made of 95% cellulose acetate having an acetyl content of 39.8% and 5% PEG surrounds the two compositions. The coating has pore sizes of 10 angstorm to 100 microns See column 10

to column 11, line 20. . Solvents for the semipermeable membrane are taught on column 20, lines 11-35. Release of the drug is taught in Figure 9. Wong teaches several shapes such as in Figure 5, wherein rather than have one port as seen in a tablet, the device as several pores to allow the passage of water. Wong teaches that the shape of the tablet and capsule shape are different, but they act in a similar manner to let fluid into the core. See column 8-9. Solvents for the semipermeable membrane are taught on column 20, lines 11-35. Release of the drug is taught in Figure 9.

Wong does not teach the instant swelling agents (sodium starch glycolate or croscarmellose) which provide the instant parameters (the instant swelling ratio and core strength). Furthermore, Wong does not teach the instant amount of tableting aid.

Stevens et al teach a delivery device with a drug and expandable excipient. The dosage form may be in tablet form. See abstract and examples. The device has an impermeable coating formed from a water-soluble material, which is preferably but not limited to capsules wherein the capsule contains the expandable excipient. See column 3, lines 13-21. The expandable excipients may also be used in a solid pharmaceutical dosage forms such as compressed powders (tablets) or cast forms. See column 4, lines 1-6. The expandable excipient is made of a solid material whose volume increases due to the absorption of water from the surrounding medium and has a water-swellable material that has the overall swelling capacity of 200-400% (col. 4, lines 44-48). The swellable materials may be chosen from water-swellable hydrogel polymers: PEO polymers with a molecular weight of 4,000-12,000 or known pharmaceutical disintegrants, i.e. sodium starch glycolate, microcrystalline cellulose, etc., which swell rapidly and completely after administration, thereby disrupting or breaking up the solid dosage form. Stevens teaches

disintegrants are not only conventionally used in solid dosages forms but they are known to enhance the delivery rate of active substances. See column 4, lines 10-30. The expandable excipients also contain wetting agents (sodium lauryl sulfate) up to 2%, lubricants such as magnesium stearate and silica up to 1%, and water-soluble sugars up to 10%. Stevens teaches the conventional hardness of a tablet is 4kg and the instant tablet may have the strength of conventional tablets or less, i.e. 2kg (col. 5, lines 5-70). The drug may be mixed with a carrier material and is positioned over the hydrogel layer (col. 6, lines 26-27). The swelling factor is taught on column 7. The device has the advantage of containing expandable excipients that are designed to improve the expulsion of the active in a particular region such as the gastric tract that has low water content. See column 5. Example 10 discloses a disintegrant tablet containing 24% low-substituted cellulose (L-HPC), 24% Avicel (microcrystalline cellulose), and 50% EXPLOTAB (sodium starch glycolate). This combination of Avicel and EXPLOTAB provide for instant swelling ratio.

Park et al teach a hydrogel composition having fast swelling and high mechanical strength. The superporous hydrogel composite is formed by polymerizing one or more ethylenically-unsaturated monomers, and a crosslinking agent, in the presence of particles of a disintegrant. The disintegrant such as crosslinked sodium carboxymethylcellulose, crosslinked sodium starch glycolate, and crosslinked PVP, rapidly absorbs water and serves to increase mechanical strength. See abstract. Park discloses that the limiting factor of hydrogels have been their slow swelling property which usually takes several hours and this it too slow for many applications when fast swelling is essential. Park discloses that although hydrogels have been successfully used as gastric retention devices that stay in the stomach for several hours, the

hydrogels have to be preswollen before administering to avoid premature emptying into the intestine. Further, Park discloses to increase swelling properties, the mechanical strength decreases; however by adding the disintegrant, the mechanical strength is increased. See column 4, lines 10-45 and column 26. Swelling ratios are taught on Table 2. Compression is taught in Figure 4A in kg/cm2. Park teaches that in the controlled drug delivery area superporous hydrogel and superporous hydrogel composites can be used as a platform for long-term oral drug delivery.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Wong et al and Steven et al and utilize the instant swelling agent. Firstly, one would have been motivated to utilize the instant swelling agent in the expandable hydrogel portion of Wong's since Stevens et al disclose the advantages of the instant swelling agent, i.e. the swelling capacity of the instant agents improve the release of an active in the gastro-intestinal tract, i.e. to provide for the complete release of the active from the dosage form. It is the examiner's position that the selection of disintegrants versus hydrogels is obvious to a skilled artisan since both hydrogels and disintegrants are utilized in the art for the same purpose, i.e. the "push" of the active out of the body and they are characterized by a specific swelling capacity to yield a certain swelling ratio. Therefore, since the swelling capacity/ratio determines the rate of release of the active agent from the device, i.e. the "push" of the active out of the dosage form, it is prima facie obvious to manipulate the selection of the swelling agent(s) and amount to yield a desired release rate. Lastly, one would expect similar results since Wong's expandable portion contains PEO polymers and Stevens teaches that the hydrogel may be PEO polymer or in an *alternative embodiment* the PEO polymers may be substituted with the instant

swelling agent to enhance to rate of deliver since the instant swelling agent rapidly absorbs water.

Additionally, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further look at Park et al and select the instant swelling agents over a hydrogel. One would have been motivated to do so since Park discloses that a fast swelling and superswelling hydrogel is important for controlled oral dosage forms, however prior art hydrogels have decreased mechanical strength as the swelling capacity is increased. Thus, Park states that instant swelling agents are improvement since they not only possess super swelling capacity but also provide increased mechanical strength to hydrogels. Therefore, one would have been motivated to utilize the instant swelling agent to not only increase the swelling capacity of the hydrogel but also increase the mechanical strength. Furthermore, Park's teaching supports the examiner's position that Stevens's expandable excipient implicitly has the instant strength.

Response to Arguments

Applicant argues that the examiner's has improperly utilized the applicant's own disclosure to provide the motivation to combine the references. Applicant argues that Stevens teaches a long list of suitable hydrogels and disintegrants; hence there is no motivation to utilize the instant two swelling agents. It is argued that a skilled artisan might equally be motivated to utilize any other disintegrant taught by Stevens. Applicant argues that Stevens teaches the use of the swelling agents for capsules and the instant invention relates to capsules. Lastly, applicant argues that Stevens is not concerned with tablet hardness and teaches away from tablet hardness.

Applicant's arguments filed 4/25/05 have been fully considered but they are not persuasive.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In instant case, Stevens discloses the well-known use of the instant disintegrants in solid dosage forms to enhance the rate of delivery of the active agent within. Therefore, the motivation to utilize the instant swelling agents is found in Stevens' disclosure *itself*.

The examiner notes that Stevens teaches many swelling agents; however, Stevens teaches in example 10 the instant swelling agent and instant tableting aid in the same amount as applicant for a tablet. Therefore, Stevens' exemplification of the EXPLOTAB (sodium starch glycolate) clearly directs a skilled artisan to utilize the instant swelling agent.

With regard to the combination of a tablet reference and capsule reference, the examiner suggests that the applicant provide evidence that the methods of making capsules and tablets are vastly different and thus one would not be able to combine the two references. Until such evidence is provided, the examiner maintains her position since Wong's expandable excipient and Stevens' expandable excipient function in a similar manner, i.e. to swell and push the active out of the dosage form. Moreover, Wong also states that although capsules and tablets have different shapes, they act in a similar manner to let fluid into the core. See column 8-9.

With regard to the unexpectedness of the tablet strength and swelling ratio, again the examiner points out that the applicant has not provided any evidence to overcome obviousness. Firstly, it is noted that Table 12 of applicant's specification discloses that EXPLOTAB and MCC provide instant swelling ratio and the examiner points out that Stevens utilizes the same combination in example 10; thus Stevens' combination of EXPLOTABLE and MCC would also have the instant swelling ratio. With regard to the tablet hardness it is the examiner's position that the core strength would implicitly flow from the combined teachings of Wong and Stevens. The examiner strongly suggests the applicant provide a showing of unexpected results to overcome the rejection based on obviousness.

Applicant argues that Parks is concerned with different swelling material than that of the instant invention. It is argued there is no motivation to combine Wong and Park and substitute Wong's PEO with the instant swelling agents.

Applicant's arguments filed 4/25/05 have been fully considered but they are not persuasive.

The examiner points out that the rejection is Wong in view of Stevens, in further view of Park. The rejection is not Wong in view of Park as argued by applicant. This is an important distinction since Stevens provides the motivation to substitute Wong's PEO hydrogel to enhance the rate of delivering the drug. However, the examiner relies on Park to provide further motivation to select instant sodium starch glycolate and sodium croscarmellose. Thus, skilled artisan would have bee motivated *after* looking at Wong and Stevens to further utilize the instant swelling agents since Park states that the instant swelling agents provide mechanical strength to the tablet unlike hydrogels.

The rejection is maintained for the reasons set for above.

Claim 57 under 35 U.S.C. 103(a) as being unpatentable over Wong et al (4,765,989) in view of Stevens et al (5,897,874), optionally in further view of Park et al (6,271,278), in further view of From hypertension to angina to Viagra (Jim Kling, Modern Drug Discovery, 1998, 1(2), pg.31, 33-34, 36, 38) is maintained.

As set forth above, Wong and Stevens teach delivery devices containing expandable excipients. Wong teaches the suitability of several drugs such as antihypertensives.

Wong and Stevens do not teach instant drug

Kling teaches Viagra as a drug for hypertension or erectile dysfunction.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use sildenafil citrate in the device of Wong or Stevens. One would be motivated to do so if one wanted to treat erectile dysfunction and it is obvious for an artisan to choose the drug depending on the symptoms and disease to be treated. Further, one would be motivated to do so with the expectation of similar results since Wong teaches the use of antihypertensives in the device.

Response to Arguments

Applicant argues that King does not cure the fatal flaws of Wong et al and Stevens et al.

Applicant's arguments filed 4/25/05 have been fully considered but they are not persuasive. The merits of Wong et al and Stevens et al have been discussed above. The examiner merely relies on King to teach the instant active agent. The choice of the active agent depends on the symptoms to be treated. Therefore, if one were motivated to treat erectile dysfunction and hypertension, then one would utilize the instant active agent.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2,7-9,12,15-32,44,49-51,56,57,63-81,88-97,101,103-108,118-122,124,130 and 131 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 5-20 of copending Application No. 10/344171. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant application is directed to controlled release drug dosage form comprising a core wherein the core comprises: a drug containing composition and a water-swellable composition in separate regions. The drug composition contains a low-solubility drug and drug-entraining agent. The swelling composition further contains at least 20% tableting aid and swelling agent. The tablet has water-permeable, water-insoluble coating with a port there through.

Co-pending application claim 1 is directed to controlled release drug dosage form comprising a core wherein the core comprises: a drug containing composition and a water-swellable composition in separate regions. The tablet has water-permeable, water-insoluble coating with a port there through. Claim 2 and 3 are directed to controlled release drug dosage

form comprising a core wherein the core comprises: a drug containing composition and a water-swellable composition in separate regions. The drug composition contains a low-solubility drug and drug-entraining agent. The swelling composition further contains a swelling agent. The tablet has water-permeable, water-insoluble coating with a port there through.

The dependent claims are directed to the same additives and the same tablet parameters.

Instant application and co-pending application are directed to a controlled release dosage form with a core that a separate swelling composition and drug composition. The difference between co-pending application is that 10/344171 is directed to a generic controlled release dosage form instant application which is directed a controlled release dosage *tablet* and independent claims specific tableting aids and swelling agents. Therefore, co-pending application encompasses the subject matter of instant application.

It should be noted that the examiner has rescinded the restriction requirement of Paper No. 5 (mailed 10/29/01); thus the double patenting rejection is proper.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 2,7-9,12,15-32,44,49-51,56,57,63-81,88-97,101,103-108,118-122,124,130 and 131 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 09/745096. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant application is directed to controlled release drug dosage form comprising a core wherein the core comprises: a drug containing composition and a water-swellable composition in

separate regions. The drug composition contains a low-solubility drug and drug-entraining agent. The swelling composition further contains at least 20% tableting aid and swelling agent. The tablet has water-permeable, water-insoluble coating with a port there through.

Co-pending application is directed to controlled release drug dosage form comprising a core wherein the core comprises: drug containing composition and a water-swellable composition in separate regions. The drug composition contains a sertraline and drug-entraining agent. The tablet has water-permeable, water-insoluble coating with a port there through.

Instant application and co-pending application are directed to a controlled release dosage form with a core that a separate swelling composition and drug composition. The difference between co-pending application is that 09/745096 is directed to a specific drug (sertraline) and instant application is directed to a generic low-solubility drug. The instant specification discloses sertraline as a low-solubility drug. Therefore, co-pending application and instant application having overlapping subject matter.

This rejection is not a provisional obviousness-type double patenting rejection because on 1/31/05 the conflicting claims were allowed.

Pertinent Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6,706,283 and application 10/799536 have been considered for double patenting issues. However, US patent '283 and application '536 do not have overlapping subject matter with the instant application for the following reasons: Firstly, the instant application is directed to a controlled release device with core comprising a separate region for a drug composition and a water-swellable composition respectively. Thus, '283 and '536 differs from the instant

application in that, although US '283 and copending '536 claims are directed to a controlled release device, the device does not have a separate region for a drug composition and the water-swellable composition respectively. Secondly, the instant application differs from US Patent and co-pending application in that the drug is not in a solid dispersion form. '283 and '536 are both *specifically* directed to a drug in a solid dispersion form.

Conclusion

None of the claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
Examiner
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SSG

Gary L. Kunz

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